

REMARKS

Favorable reconsideration, reexamination, and allowance of the present patent application are respectfully requested in view of the foregoing amendments and the following remarks.

Withdrawal of Claims

Applicant acknowledges the withdrawal of Claims 15-22 from consideration at this time, pursuant to the Restriction / Election requirement in the Office Action and the undersigned's verbal election. Applicant has cancelled the non-elected claims, yet does so without disclaimer of the subject matters thereof; Applicant expressly reserves the right to file one or more Divisional patent applications to further pursue the subject matters of Claims 15-22.

Objection to the Claims

At page 3 of the Office Action, Claim 3 was objected to because it included a typographical error. Applicant respectfully requests reconsideration of this objection, in view of the foregoing amendment to Claim 3 by which "or" has been replaced with "and".

Rejection under 35 U.S.C. § 102

In the Office Action, beginning at page 3, Claims 1-3 and 8 were rejected under 35 U.S.C. § 102, as reciting subject matters that allegedly are anticipated by Published U.S. Patent Application No. 2002/0161414, invented by Flesler *et al.* ("Flesler"). Applicant respectfully requests reconsideration of this rejection.

Applicant first notes that Claim 2 has been cancelled, and some of its subject matter has been added to Claim 1.

This application describes examples of methods and devices embodying principles of the present invention. As described at length in this application, long term, fixed, internal reduction of blood flow to the small intestine of a patient can reduce the function of the small intestine to digest food, thereby reducing the caloric intact possible from that food. As mentioned in this application, obesity can be affected by vascular procedures because weight loss is associated

with chronic mesenteric ischemia. By placing a narrowing, partial blockage, stenosis, or blood-flow restrictor into an artery that supplies blood to the duodenum, the lower intestine, jejunum, ileum, or combinations thereof, mesenteric ischemia can be induced. The blood flow through arteries that are collateral to the superior mesenteric artery, *e.g.*, the gastroduodenal and inferior mesenteric arteries, is optionally also reduced, so that collateral blood flow does not make up for the blood flow reductions in the superior mesenteric artery. While these organs typically have more than one blood supply, restriction of the blood supply by forming a partial blockage in one or more select arteries can induce mesenteric ischemia, thus reducing the effectiveness of the organ to digest food, and consequently reducing the patient's intake of compounds from the food the patient has ingested.

Claim 1 relates to a method of treating morbid obesity in a patient comprising reducing gastric blood flow, duodenal blood flow, mesenteric blood flow, jejunal blood flow, ileal blood flow, or combinations thereof, in the patient, including placing a blood flow reducing device inside an artery that carries blood to the small intestine.

The prior art, including *Flesler*, fails to identically disclose or describe methods as recited in the pending claims.

Flesler describes systems and methods allegedly useful for treating obesity in a patient. *Flesler* uses intermittent electrical stimulation on the exterior of "or in the vicinity of" (para. [0113]) the superior mesenteric artery 110 to intermittently narrow the mesenteric arteries, only after meals. Because *Flesler* applies electrical stimulation to the muscle cells of the artery, whatever constriction *Flesler* may be able to achieve, can't be controlled. That is, the amount of narrowing occurring in the arteries would not be apparent to any observer, may be more than is safe (leading to clotting or acute blockage of the arteries with a high risk of bowel infarction/death and patient death), or less than is necessary to achieve the goal of incomplete absorption or hindered digestion. That is, the amount of narrowing of the artery by electrical stimulation is not consistent and reproducible. *Flesler* acknowledges and prefers that any reduction in the blood flow through the artery is discontinuous, variable, and not permanent: "The constriction produced by apparatus 118 preferably transiently and controllably reduces the

blood flow to small intestine 120. . .”. Para. [0113].

Flesler also emphasizes that his methods are to be used only with meals, and are not permanent solutions:

Alternatively or additionally, operation of apparatus 118 is initiated or supplemented responsive to a parameter of the contents of small intestine 120, such as an indication by sensors 172 of the lipid concentration thereof. Further alternatively or additionally, the patient is enabled to activate apparatus 118 (e.g., during and after eating dessert, or for a determined time period when the patient is going to sleep) and to deactivate the apparatus (e.g., when the patient has a headache, or has orally taken a medication). Still further alternatively or additionally, apparatus 118 is activated a fixed or variable time (e.g., 10-30 minutes) following initiation of a meal, when it is expected that some digestive products will have reached the small intestine.

Para. [0116].

Furthermore, the Office Action acknowledges that *Flesler*'s method is performed exterior to the artery; at page 3, the Office Action states that *Flesler*'s devices are placed around the artery. Accordingly, *Flesler* fails to identically disclose a method including each and every feature recited in Claim 1.

For at least the foregoing reasons, Applicant respectfully submits that the subject matters of Claims 1, 3, and 8 are not anticipated by *Flesler*, are therefore not unpatentable under 35 U.S.C. § 102, and therefore respectfully requests withdrawal of the rejection thereof under 35 U.S.C. § 102.

Rejection under 35 U.S.C. § 103(a)

In the Office Action, beginning at page 4, Claims 4-6, 9, 10, and 12-14 were rejected under 35 U.S.C. § 103(a), as reciting subject matters that allegedly are obvious, and therefore allegedly unpatentable, over *Flesler* in view of the disclosure of U.S. Patent No. 6,120,534, issued to Ruiz. Additionally, Claim 7 was rejected under section 103(a) as reciting subject matter that allegedly is obvious, and therefore allegedly unpatentable, over *Flesler* in view of the disclosure of U.S. Patent No. 3,730,186, issued to Edmunds, Jr., *et al.* (“Edmunds”); and, lastly, Claim 11 was rejected under section 103(a) as reciting subject matter that allegedly is obvious,

and therefore allegedly unpatentable, over *Flesler* and *Ruiz* in view the disclosure of U.S. Patent No. 5,690,644, issued to Yurek *et al.* ("Yurek"). Applicant respectfully requests reconsideration of this rejection.

Applicant first notes that Claim 7 has been cancelled; its rejection is moot.

Flesler fails to identically disclose or fairly suggest the subject matters recited in the pending claims, and *Ruiz* fails to make up for the deficiencies of *Flesler* with respect to the subject matters of the claims. *Ruiz* describes a blood flow restriction stent 10 with an adjustable internal diameter, which is installed in the pulmonary artery PA of a patient.

Applicant respectfully submits that one of ordinary skill in the art, upon a full and fair reading of *Flesler* and *Ruiz*, would not be motivated to replace *Flesler*'s external (to the artery) and intermittent blood flow reduction methodology with an internal (to the artery), permanent blood flow restrictor, such as generally disclosed in *Ruiz*. *Flesler*, as discussed above, is singularly interested in only discontinuously and intermittently restricting the blood flow to the small intestine, timed to correspond to the presence of food in the small intestine; this is why *Flesler* suggests the placement of sensors in the body to detect food, and/or to configure the logic of the apparatus to permit its activation in synch with a meal. *Flesler* is also only concerned with modifying the blood flow to the small intestine by external stimulation of the artery that supplies blood to the small intestine, and not to an internal (to the artery) modification. Nowhere does *Ruiz* disclose or suggest that his stent should be used to treat obesity in a patient. *Yurek*'s disclose adds nothing to this analysis.

Applicant respectfully submits, therefore, that a person of ordinary skill in the art, at the time of Applicant's invention, would not have looked to *Ruiz* for a stent to restrict blood flow for *Flesler*'s method. Because *Flesler* is only concerned with externally implemented, intermittent reduction in the blood flow to an artery, and *Ruiz*'s stent is a permanent, internal solution, *Flesler* teaches directly away from the addition or substitution of *Ruiz*'s stent. Nowhere does *Flesler* indicate or suggest that permanent, internally achieved blood flow reduction is desirable, and instructs the ordinarily skilled artisan that intermittent, externally achieved blood flow reduction (the opposite of that claimed) is how to treat obesity. *Ruiz* is, of course, completely ignorant of

the possibility of using a reduction in blood flow to particular arteries to treat obesity, and therefore understandably fails to provide any motivation, suggestion, or guidance to use his stent in *Flesler*'s method.

The subject matter of Claim 14 is an example of how *Flesler* teaches away from the claimed combinations. Claim 14 relates to the method of Claim 10, and further requires adjusting the second portion of the endograft to achieve a pressure change within a desired range so that abdominal pain not related to meals does not occur. Literal recitation of this subject matter has been added to the specification, at paragraph [0053]; as well known to those of ordinary skill in the art, the reduction in the flow cross section in a fluid lumen throttles the flow, creating a pressure drop across the flow restriction with a corresponding decrease in the flow through the lumen. Applicant has merely elected to articulate this inherent physical fact in the specification.

Flesler completely fails to identify non-meal related pain as a problem, because his method is entirely meal-oriented; in view of the several-fold increase in blood supply to the small intestine during meal digestion, and the fact that *Flesler*'s method does nothing to the blood supply at other times, *Flesler* (and the skilled artisan) would not expect the patient to experience pain outside of mealtimes to begin with. There is nothing in *Flesler* or *Ruiz* to suggest that they would associate non-mealtime pain with the reduction in small intestine blood flow, or to suggest that alleviation of that pain could be achieved by changing the permanent, invariable blood flow restriction to the small intestines. Analysis of the subject matter of Claim 14, like those of the other pending claims, against *Flesler* and *Ruiz* further supports the patentability of Claim 1 *et seq.*

For at least the foregoing reasons, Applicant respectfully submits that the subject matters of Claims 4-7 and 9-14, each taken as a whole, would not have been obvious to one of ordinary skill in the art at the time of Applicant's invention, are therefore not unpatentable under 35 U.S.C. § 103(a), and therefore respectfully requests withdrawal of the rejection thereof under 35 U.S.C. § 103(a).

New Claims

New Claims 23-25 have been added. Claims 23-25 are modeled on original Claim 1: Claim 23 requires that the reduction in blood flow be permanent; Claim 24 requires that the reduction in blood flow be by a fixed, invariable amount; and Claim 25 requires that the reduction in blood flow be continuous for a time effective to reduce the patient's weight. For the same reasons presented above with respect to the patentability of the pending claims over the improper hypothetical combination of *Flesler* and *Ruiz*, Claims 23-25 are also allowable; an early indication of the allowability of these claims is earnestly solicited.

Conclusion

Applicant respectfully submits that the present patent application is in condition for allowance. An early indication of the allowability of this patent application is therefore respectfully solicited.

If Mr. Prebilic believes that a telephone conference with the undersigned would expedite passage of this patent application to issue, he is invited to call on the number below.

It is not believed that extensions of time are required, beyond those that may otherwise be provided for in accompanying documents. If, however, additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and the Commissioner is hereby authorized to charge fees necessitated by this paper, and to credit all refunds and overpayments, to our Deposit Account 50-2821.

Respectfully submitted,

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